SEP 1 4 2005

K 052324

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SYNERON MEDICAL Ltd. Polaris LV / LVA Applicator

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Syneron Medical Ltd., Tavor Bld.,

Industrial Zone

Yokneam Illit, Israel

Tel. +972.4.909-6200, Fax +972.4. 909-6202

Name of the Device: Polaris LV , LVA Applicator

Predicate Devices: This is a Special 510(k) for the Polaris LV that was cleared under K030186.

Device Description: The Polaris LV is a device that is used for treatment of vascular lesions. The Polaris LV treatment is based on the principle of selective (electromagnetic) thermolysis. According to this principle, parameters of optical and RF energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively damage to the hair follicle without damaging the surrounding tissues.

The Polaris LV is intended for use in dermatology for treatment of vascular lesions.

The modifications to the Polaris LV do not affect the intended use or alter the fundamental scientific technology of the device. The only device modification is increasing the laser energy density output, still with in the range of predicate devices.

There are no labeling changes that affect the intended use of the device. The device modifications raise no new issues of safety or effectiveness.

August 22 20005

Amir Waldman

Dr. Amir Waldman

VP regulatory & clinical affairs

Syneron Medical Ltd.

Name of Manufacturer: Syneron Medical Ltd.
Laser Model Name and Number: Polaris LV
Laser Type: -(Circle all that apply)-

Alexandrite, Argon, CO_2, Copper-Vapor, (Diode), Dye, Nd:YAG, Erb:Y
Ho1:YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other___

Indications in this Application: Treatment for dermatological Vascular lesions.

List of Examples:

FDA Document Control Number: K 052324
FDA Product Code: GEX
Reviewer Computer Initials: SPB
Date of Clearance Letter:

Basis of Approval: -(Circle all that apply)-

Predicate Device (PD), Clinical Data (CD), Animal Data (AI
Specifications (SPECS), Bench Test Data (BTD), Historical Informati
(HI), Other

Description of Laser:

Operation Modes: -(Circle all that apply)-

CW, (Pulsed), Q-Switched, Mode Locked, Contact, Free beam, Other

Wavelength(s) in Nanometers: 780 - 980
Power/Energy Range(watts/joules): 350 J/cm^2 (optical) + 100 J/cm^3 (RF) Pul
Width: 100 msec Repetiti
Rate: 1 Hz Delivery System(s
Laser beam is transmitted through the light guide out of the applicator.

Comments: Laser and RF Energy are combined for the treatment. This special 510(K) is for enhancing the optical fluence from 140 to 350 J/cm^2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Dr. Amir Waldman
VP Regulatory & Clinical Affairs
Syneron Medical Ltd., Tavor Building
Industrial Zone
P.O.B. 550
Yokneam Illit,
Israel 20692

Re: K052324
Trade/Device Name: Polaris LV, LVA Applicator
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, GEI
Dated: August 22, 2005
Received: August 25, 2005

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bruelmd for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052324

Device Name: Polaris LV, LVA Applicator

Indications For Use: The Polaris LV is intended for use in dermatology for treatment of vascular lesions.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruchup for NXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052324